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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,493	03/23/2000	Oscar Jimenez	20037	1061

7590                    04/08/2003

Thomas R Vigil  
c/o Vigil & Associates  
836 South Northwest Highway  
Barrington, IL 60010

EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
3763	7

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	<b>Applicant(s)</b>	
	09/533,493	JIMENEZ, OSCAR <i>MF</i>	
<b>Period for Reply</b>	Examiner	Art Unit	
	Jeremy T. Thissell	3763	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>19 April 2002</u> .			
2a) <input checked="" type="checkbox"/> This action is FINAL.                    2b) <input type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>11-22</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>11-22</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input checked="" type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____ .			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> .		6) <input type="checkbox"/> Other: _____ .	

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The specification is objected to, because the listing of references in the specification is not a proper information disclosure statement. The list must be deleted from the specification.

### ***Product by Process Claims***

“... If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to Applicant’s claim limitations “extrusion” (e.g. claim 12, line 3), and “welded on or molded on” (e.g. claim 13), these limitations claim a product by process as discussed in the preceding paragraph. The prior art disclosing the same structure, these claims are unpatentable. However, for the record, the Examiner would like to point out that connection of catheter segments by welding or molding is well-known in the art and is taught by Griep (US 5,163,431).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Tovey (US 5,445,140).

Tovey teaches all the claimed subject matter including a catheter with a shape memory tip as claimed (abstract; and col. 3, lines 28 and 44).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140 in view of Bley et al (US 5,762,630) and Schroeppel (US 6,024,764).

Tovey teaches all the claimed subject matter including a catheter with a shape memory tip as claimed (abstract; and col. 3, lines 28 and 44). However, Tovey does not teach the claimed shore D hardnesses or the tubular member having a shape memory outer “jacket”, or the braided mesh reinforcing layer. Bley teaches a shape memory catheter wherein the disclosed material comprises polyurethane (col. 4, lines 44-45) is radiopaque (col. 5, line 40), and is taught to have a durometer of 78 D when its temperature is below the glass transition temperature ( $T_g$ ) and a durometer of 25 D

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when its temperature is above  $T_g$ . Bley teaches that  $T_g$  is between 15-35° C, and further states that materials with varying glass transition temperatures may be used (col. 5, lines 17-22).

In addition, Bley teaches that a suitable material is MM-3510 made by Mitsubishi Heavy Industries (col. 4, line 45), which is substantially similar to MM-3500 which is also a polyurethane-based material made by Mitsubishi and is disclosed as the material of choice by applicant on page 3 of their own specification.

It would have been obvious to one of ordinary skill in the art to choose a material with the claimed properties (which are only slightly different than those discussed by Bley), particularly in view of Bley's statement in col. 5, lines 17-22. Further, it would have been obvious to one of ordinary skill in the art to use such a material for the device of Tovey in order to insert the device into the tortuous passageways of the human anatomy.

Schroepel teaches a shape memory outer jacket and also a braided reinforcement layer for an implantable tubular device such as a catheter. (col. 1, lines 9-10) It would have been obvious to include the jacket and layer of Shroepel on the device of Tovey as modified by Bley, particularly since part of the catheter in Tovey is already of a shape memory material, in order to facilitate insertion of the device into body lumens as is well-known in the art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140) in view of Bley et al (US 5,762,630).

See combination of Bley with Tovey discussed above.

Claims 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140 in view of Schroepel (US 6,024,764).

See combination of Schroepel with Tovey discussed above.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,1400 in view of Bley et al (US 5,762,630) and Schroepel (US 6,024,764) as applied to claim 11, and further in view of Griep (US 5,163,431).

Tovey teaches all the claimed subject matter except for the distal end of the tubular body being tapered. Griep teaches that the distal end of the tubular body is tapered (e.g. element 15; figures 1 and 2. Mating conical sections are a well-known mechanism of interfitting tubular members and would have been an obvious way to connect the tip of Tovey, particularly in view of Tovey's teaching that other methods for securing the sections will be apparent to those skilled in the art (col. 3, lines 14-19).

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the completely new claim set, and new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt  
April 6, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700